UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/375,759	12/01/2011	Vega Masignani	529552004430	7809

20872 7590 04/10/2017

MORRISON & FOERSTER LLP
425 MARKET STREET
SAN FRANCISCO, CA 94105-2482

EXAMINER
OGUNBIYI, OLUWATOSIN A

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
04/10/2017	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

EOfficeSF@mofo.com
PatentDocket@mofo.com
pair_mofo@firsttofile.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte VEGA MASIGNANI, MICHELE ANNE BAROCCHI, MONICA MOSCHIONI, and PAOLO RUGGIERO

Appeal 2014-004949
Application 13/375,759
Technology Center 1600

Before JEFFREY N. FREDMAN, ULRIKE W. JENKS, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal[1] under 35 U.S.C. § 134 involving claims to a method of raising an immune response. The Examiner rejected the claims as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Statement of the Case

Background

"*S. pneumoniae* has a pilus known as pilus-1 encoded by a 14-kb islet (PI-I) having seven genes encoding: the RlrA transcriptional regulator, three pilus subunits with LPXTG-type cell wall sorting signals, and three sortase enzymes involved in synthesis of the pilus polymer and in the incorporation

---

[1] Appellants identify the Real Party in Interest as Novartis AG (*see* App. Br. 2).

of ancillary pilus components" (Spec. 1:5–8). "RrgB is the major subunit that forms the backbone of the structure, while the other two pilins (RrgA, RrgC) are ancillary structural proteins" (Spec. 1:8–9).

> It has been found that serum raised against a given RrgB clade is active against pneumococci which express that clade, but is not active against strains which express one of the other two clades *i.e.* there is intra-clade cross-protection, but not inter-clade cross-protection. According to the invention, therefore, an immunogenic composition includes at least two different clades of RrgB.

(Spec. 6:10–13).

The Claims

Claims 7 and 9–11 are on appeal. Claim 7 is representative and reads as follows:

> 7. A method of raising an immune response in a mammal comprising administering to the mammal an effective amount of an immunogenic composition comprising at least two of:
>
> (a) a first polypeptide comprising a first amino acid sequence, where the first amino acid sequence comprises an amino acid sequence (i) having at least 90% sequence identity to SEQ ID NO: 1 and/or (ii) consisting of a fragment of at least 7 contiguous amino acids from SEQ ID NO: 1;
>
> (b) a second polypeptide, comprising a second amino acid sequence, where the second amino acid sequence comprises an amino acid sequence (i) having at least 90% sequence identity to SEQ ID NO: 2 and/or (ii) consisting of a fragment of at least 50 contiguous amino acids from SEQ ID NO: 2; and/or
>
> (c) a third polypeptide, comprising a third amino acid sequence, where the third amino acid sequence comprises an amino acid sequence (i) having at least 90% sequence identity to SEQ ID NO: 3 and/or (ii) consisting of a fragment of at least 29 contiguous amino acids from SEQ ID NO: 3.

The issue

The Examiner rejected claims 7 and 9–11 under 35 U.S.C. § 102(b) as anticipated by Telford[2] (Ans. 3–4).

The Examiner finds Telford teaches

> a method of raising an immune response in a mammal . . . comprising administering combinations of two or more proteins selected from a group of proteins which comprises at least two of the proteins of instant claim 1 wherein the at least two proteins which are identical to those listed in instant claim 7 are SP0463 (SEQ ID NO: 85), ORF4_6BF (SEQ ID NO: 196), ORF4-6BSP (SEQ ID NO: 203), ORF4-670 (SEQ Id NO: 174), ORF4-14CSR (SEQ ID NO: 217), ORF4_23FTW (SEQ ID NO: 231).

(Ans. 3–4).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Telford anticipates the claims?

Findings of Fact

1. Telford teaches the "GBS AI proteins of the invention may be used in immunogenic compositions for prophylactic or therapeutic immunization against GBS infection" (Telford ¶ 20).

2. Telford teaches the "immunogenic compositions may also be selected to provide protection against an increased range of GBS serotypes and strain isolates. For example, the immunogenic composition may comprise a first and second GBS AI protein" (Telford ¶ 21).

---

[2] Telford et al., US 2006/0165716 A1, published July 27, 2006 ("Telford").

3. The Examiner finds:

> SP0463 (SEQ ID NO: 85) is 100% identical to SEQ ID NO: 1 and/or consists of a fragment of at least 7 contiguous amino acids from SEQ ID NO: 1. See appendix A.
>
> ORF4_6BF (SEQ ID NO: 196) is 100% identical to SEQ ID NO: 2 and/or consists of a fragment of at least 50 contiguous amino acids from SEQ ID NO: 2. See appendix B
>
> ORF4-6BSP (SEQ ID NO: 203) is 100% identical to SEQ ID NO: 2 and/or consists of a fragment of at least 50 contiguous amino acids from SEQ ID NO: 2. See appendix C
>
> ORF4-670 (SEQ Id NO: 174) is 100% identical to SEQ ID NO: 2 and/or consists of a fragment of at least 50 contiguous amino acids from SEQ ID NO: 2. See appendix D
>
> ORF4_23FTW (SEQ ID NO: 231) is 100% identical to SEQ ID NO: 3 and/or consists of a fragment of at least 29 contiguous amino acids from SEQ ID NO: 3. See appendix E.

(Ans. 4).

4. Telford teaches:

> S. *pneumoniae* AI surface proteins are preferred proteins for use in the immunogenic compositions of the invention. In one embodiment, the compositions of the invention comprise combinations of two or more S *pneumoniae* AI surface proteins. Preferably such combinations are selected from two or more of the group consisting of SP0462, **SP0463**, SP0464, orf3_670, **orf4_670**, orf5_670, ORF3_14CSR, ORF4_14CSR, ORF5_14CSR, ORF3_19AH, ORF4_19AH, ORF5_19AH, ORF3_19FTW, ORF4_19FTW, ORF5_1 gFTW, ORF3_23FP, ORF4_23FP, ORF5_23FP, ORF3_23FTW, **ORF4_23FTW**, ORF5_23FTW, ORF3_6BF, **ORF4_6BF**, ORF5_6BF, ORF3_6BSP, **ORF4_6BSP**, ORF5_6BSP, ORF3_9VSP, ORF4_9VSP, and ORF5_9VSP.

(Telford ¶ 111; emphasis added to identify proteins listed as meeting requirements of claim 7 by Examiner; *cf.* Ans. 8).

Principles of Law

> For the purposes of whether they are anticipatory, lists and genera are often treated differently under our case law. *Compare Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1376 (Fed.Cir.2005) (rejecting "the notion that [a compound] cannot anticipate because it appears without special emphasis in a longer list") with *Atofina v. Great Lakes Chem. Corp.,* 441 F.3d 991, 999 (Fed.Cir. 2006) ("It is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus.").

In re Gleave, 560 F.3d 1331, 1337 (Fed. Cir. 2009).

Analysis

We adopt the Examiner's findings of fact and reasoning regarding the scope and content of the prior art (Ans. 3–4; FF 1–4) and agree that the claims are anticipated by Telford. We address Appellants' arguments below.

Appellants contend "Telford *et al.* in fact disclose a group of ***30 preferred proteins***, from among which ***two or more*** proteins are to be selected to form immunogenic compositions" (App. Br. 4). Appellants contend

> Thus, the paragraphs cited by the Examiner at best disclose a broad genus of protein combinations. Even the smallest genus of just the pairwise combinations (870) is too large to envision one of the small number of pair-wise combinations that are relevant to the claims. Based upon the examiner's assertion, there are only seven possible pair-wise combinations that meet the limitations of the claims . . . The Examiner has provided no reason for why a person of skill would have selected one of these specific combinations from among the 870 possible pair wise compositions disclosed by Telford *et al.*

(App. Br. 5). Appellants contend "that, in this case, the class of possible protein combinations disclosed by Telford *et al.* is not as limited as the class of about 20 compounds in *In re Petering* and that a person of ordinary skill could *not at once envisage* the exact combinations suggested by the Examiner" (App. Br. 6).

We do not find these arguments persuasive because Telford teaches that every combination of two proteins selected from the listed group (FF 4) would have been expected to function as an immunogen (FF 2). This reasoning is consistent with *Blue Calypso* and *Kennametal*, where

> The party challenging the claim's patentability argued, and the Board accepted, that the reference anticipated each of the numerous possibilities that resulted from the permutations of the options disclosed in the reference. . . . In affirming the Board's anticipation finding, we noted that a reference need not always include an express discussion of the actual combination to anticipate. . . . Instead, a reference may still anticipate if that reference teaches that the disclosed components or functionalities may be combined and one of skill in the art would be able to implement the combination.

Blue Calypso, LLC v. Groupon, Inc., 815 F.3d 1331, 1343–44 (Fed. Cir. 2016) (*analyzing Kennametal, Inc. v. Ingersol Cutting Tool Co.*, 780 F.3d 1376 (Fed. Cir. 2015). Here, Telford clearly teaches the disclosed immunogenic components, requires that the immunogenic components be combined, and evidences that the skilled artisan would be able to implement the combination (FF 1–4).

Appellants contend

> the present facts, where there are hundreds of pairwise combinations, are much more akin to the facts in *Impax Laboratories, Inc., v. Aventis Pharmaecuticals Inc.,* 468 F.3d 1366, 81 U.S.P.Q.2D (BNA) 1001 (Fed. Cir. 2006). . . .

> Telford et al. does not anticipate the pending claims as one of skill in the art because one of skill in the art could not "at once envisage" a combination that is relevant to the pending method claims given the hundreds of pairwise combinations.

(Reply Br. 5–6).

We do not find this argument persuasive because in *Impax*, there were other issues besides the combination concerns. Indeed, as discussed in *Wrigley*, the "issue in *Impax* was whether the use of the drug riluzole for treating amyotrophic lateral sclerosis ("ALS") was anticipated . . . there are important distinctions between that case and this one. . . . the only mention of riluzole in the prior art reference in *Impax* was to disclaim it from the disclosed invention." *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1361–62 (Fed. Cir. 2012). Thus, unlike the instant case or *Wrigley*, *Impax* disclaimed the drug from the disclosed invention, as well as not providing dosage information.

Wrigley itself also supports the Examiner's anticipation rejection. In *Wrigley*, the Shahidi patent disclosed "several categories of components that can be included in the compositions" including "WS–3 and WS–23 as two of three "particularly preferred cooling agents'" and "menthol as one of 23 listed flavoring agents." *Wrigley* found the "question for purposes of anticipation is therefore whether the number of categories and components in Shahidi was so large that the combination of WS–23 and menthol would not be immediately apparent to one of ordinary skill in the art." *Id.* at 1361. *Wrigley* concluded that "the Shahidi reference clearly identifies the combination." *Id.* at 1362.

The same reasoning applies here. Where the list of flavoring agents included 23 members in *Wrigley*, Telford lists 30 different specific surface

proteins, and specifically teaches combinations of "two or more of the group" (FF 4). Because Telford teaches all of the selections in a single list in a single paragraph, rather than having to combine teachings from different parts of the patent reference as in *Wrigley*, Telford provides a stronger anticipation fact pattern than *Wrigley*. Thus, the specific combinations from Telford's list anticipate the claims.

Appellants also contend the "claimed methods produce a surprisingly superior result which are not taught or even suggested by Telford *et al.*" (App. Br. 7).

We find this argument unpersuasive because unexpected results, a type of secondary consideration, are not an element of an anticipation analysis. *See Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1364 (Fed. Cir. 2008) ("[S]econdary considerations are not an element of a claim of anticipation").

Conclusion of Law

The evidence of record supports the Examiner's conclusion that Telford anticipates the claims.

SUMMARY

In summary, we affirm the rejection of claim 7 under 35 U.S.C. § 102(b) as anticipated by Telford. Claims 9–11 fall with claim 7.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED